DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration Rockville MD 20857

JUL - 2 1999

6549 '99 JUL -6 P1:41

The Honorable Joseph I. Leiberman United States Senate Washington, D.C. 20510-0703

Dear Senator Leiberman:

Thank you for your letter of June 16, 1999 on behalf of Ms. Sheila Baummer of Naugatuck, Connecticut, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

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We have forwarded Ms. Baummer's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,

elinda K. Plaisier

Interim Associate Commissioner for Legislative Affairs

Enclosures

cc: Dockets Management Branch

(98N-1038)

JOSEPH I. LIEBERMAN CONNECTICUT

COMMITTEES:
ARMED SERVICES
ENVIRONMENT AND PUBLIC WORKS
GOVERNMENTAL AFFAIRS
SMALL BUSINESS

United States Senate

WASHINGTON, DC 20510-0703

June 16, 1999

SENATE OFFICE BUILDING
WASHINGTON, DC 20510
*202) 224-4041
STATE OFFICE
ONE STATE STREET
14TH FLOOR

ONE STATE STREET
14TH FLOOR
HARTFORD, CT 06103
860-549-8463
TOLL FREE: 1-800-225-5605

INTERNET ADDRESS: senator_lieberman@lieberman.senate.gov

HOME PAGE: http://www.senate.gov/~lieberman,

Dr. Jane E. Henney Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Dr. Henney:

I'm enclosing a copy of a letter which I recently received from one of my constituents. Sheila Baummar, who expressed concern that the FDA may be considering removing the labeling requirements for irradiated foods.

My constituents feels such a move would be unsafe and that consumers deserve to know how food products have been prepared and treated prior to purchase.

I would greatly appreciate it if you would provide me with a response which addresses the concerns my constituent has raised.

Thank you for your attention to this matter.

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No. 99-4223

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May 14, 1999

Senator Joseph Lieberman 1 State St. Suite 1420 Hartford, CT 06103

Dear Senator Lieberman;

I am writing to you regarding two important issues. First, I would like to lend my full support of myself and my family toward your efforts to improve the ratings of the entertainment industry. Also I support the new initiative regarding the internet. The internet has become a wonderful yet potentially disastrous tool.

The second issue regards an alarming development at the Food and Drug Administration. Apparently under pressure from food manufactures and the nuclear industry they are considering removing the labeling requirements for irradiated foods. The public only has until May 18th to comment on this rule. The ruling would allow the symbol known as the radura and the statement that declares the food has been "treated with radiation" or "treated by irradiation" to be eliminated from foods.

The FDA has ruled that foods can be treated with irradiation but in my opinion this is unsafe and I will never knowingly buy food treated this way for myself or my family. Most people would readily agree it is our right to buy whatever food we choose. Why would we give up the right to choose how this food is prepared and treated before we purchase it? We have a labeling system to tell us ingredients, fat content, calories etc. Why would the FDA think we wouldn't be interested in the fact that it has been irradiated or not?

As your constituent and as a concerned citizen I urge you to write to the FDA and ask them to continue to require the clear and concise labeling of irradiated foods and please find out why the comment period on this issue has been so short. I have enclosed my letter to the FDA for your reference.

appreciate your attention to this matter.

Sincerely,

Sheila Baummer 211 Field St.

Naugatuck, CT 06770

May 14, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

Re: Docket No. 98N-1038, Irradiation in the Production, Processing, and Handling of Food

To whom it may concern:

I support the recommendation by the Center for Science in the Public Interest regarding the labeling of irradiated foods:

"any foods, or any food containing ingredients that have been treated by irradiation, should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale."

I believe the terms "treated with radiation" or "treated by irradiation" should be retained. Any phrase involving the word "pasteurized" is misleading because pasteurization is an entirely different process of rapidly heating and cooling.

I am not familiar with the "radura" as a symbol that means the food has been irradiated. I believe that along with retaining the information on the label as stated previously, there should be an extensive campaign to inform the public exactly what this symbol stands for. The campaign was very successful for the new nutritional labeling and could be equally effective for irradiation. The FDA primary goal should be the protection and education of the public. Consumers cannot make informed choices on their food without proper and accurate labels.

I urge you to extend the comment period past its current end date of May 18, 1999 and release additional press releases to make this issue well know throughout the country. This will allow concerned citizens more time to respond to this important issue. This issue and the replies placed on the internet would keep a large portion of the public informed of this issue and the process.

I thank you for taking into account my opinions on this subject and I'm sure they will be considered during this process.

Sincerely,

Sheila Baummer 211 Field St. Naugatuck, CT 06770

Cc: Senators: Chris Dodd, Joseph Lieberman, Representatives: James Maloney